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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,414	09/06/2000	Moshe Szyf	2055MC/48896	9016

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EXAMINER

WALICKA, MALGORZATA A

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/554,414

Applicant(s)

SZYF ET AL.

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- Group I, claim(s) 1 (partially), drawn to human DNA demethylase having the amino acid sequence of SEQ ID NO: 2, 4.
- Group II, claim(s) 1 (partially), drawn to mouse DNA demethylase having the amino acid sequences of SEQ ID NO: 6 and 8.
- Group III, claim(s) 2 and 10-11, 13 and 16 drawn to human cDNA of SEQ ID NO: 1 and 3 and recombinant production of the enzyme.
- Group IV, claim(s) 3, drawn to mouse cDNA of SEQ ID NO: 5 and 7.
- Group V, claim(s) 4-8, drawn to use of demethylase cDNA to alter DNA methylation patterns *in vitro* in cells or *in vivo* in humans.
- Group VI, claim(s) 9 (partially), 27 (partially) and 30, drawn to use of human demethylase or its cDNA for changing the state of differentiation of a cell to allow for gene therapy, stem cell selection or cell cloning.
- Group VII, claim(s) 9 (partially), 27 (partially) and 30, drawn to use of human demethylase or its cDNA for changing the state of differentiation of a cell to allow for gene therapy, stem cell selection or cell cloning.

- Group VII, claim(s) 9 (partially), 27 (partially), drawn to use of mouse demethylase or its cDNA for changing the state of differentiation of a cell to allow for gene therapy, stem cell selection or cell cloning.
- Group VIII, claim(s) 12 (partially) and 14, drawn to producing antibody against human demethylase.
- Group IX claim(s) 15, drawn to use of human demethylase cDNA in two-hybrid system in yeast to identify protein interaction with demethylase.
- Group X, claim(s) 17 (partially), drawn to an assay for screening of inhibitors of the human demethylase, SEQ ID NO: 2 and 4.
- Group XI, claim(s) 17 (partially), drawn to an assay for screening of inhibitors of the mouse demethylase SEQ ID NO: 6 and 8.
- Group XII, claim(s) 18, drawn to the diagnostic assay of cancer in a patient.
- Group XIII, claim(s) 19-25 (partially), drawn to use of antagonist or inhibitor of human DNA demethylase for the manufacture of a medicament for cancer treatment.
- Group XIV, claim(s) 19-25 (partially), drawn to use of antagonist or inhibitor of mouse DNA demethylase for the manufacture of a medicament for cancer treatment.
- Group XV, claim(s) 27 (partially) and 30, drawn to use of human demethylase and its cDNA for changing the state of differentiation of a cell to allow gene therapy, stem cell selection or cell cloning.

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Group XVI, claim(s) 27(partially), drawn to use of mouse demethylase for changing the state of differentiation of a cell to allow gene therapy, stem cell selection or cell cloning.

Group XVII, claim(s) 26, drawn to use of human demethylase for removing methyl groups on DNA *in vitro*.

Group XVIII, claim(s) 28 (partially) and 31, drawn to use of human demethylase or its DNA for inhibiting methylation in cancer cells using vector mediated gene therapy.

Group XIX, claim(s) 28 (partially), drawn to use of its mouse demethylase inhibiting methylation in cancer cells.

Group XX, claim(s) 29, drawn to a diagnostic assay of cancer involving determining the level of expression of DNA demethylase.

The inventions are drawn to the following products: DNA demethylase of *Homo sapiens*, its encoding DNA and DNA demethylase of mice and its encoding DNA (Groups I-IV). Groups I-IV are drawn to four independent chemical compounds. Groups V to XX are drawn to 16 independent methods of use of the enzyme, its cDNA, as well as enzyme inhibitors. 37 CFR 1.475 does not provide for **multiple products** or **methods** within a single application and therefore unity of invention is lacking with regard to Groups I-XX. Thus, restriction is proper.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.


If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.

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Patent Examiner

  
TEKCHAND SAIDHA  
PRIMARY EXAMINER